

JUL 11 2007

PATENT  
Docket No. 134.01930101

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): SPARER et al. ) Group Art Unit: 1618  
 Serial No.: 10/640,853 )  
 Confirmation No.: 9178 ) Examiner: James W. Rogers  
 Filed: August 13, 2003 )  
 For: ACTIVE AGENT DELIVERY SYSTEMS, MEDICAL DEVICES, AND  
 METHODS

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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Appellants hereby request a Panel Review of the final rejection, dated April 11, 2007, in the above-identified application. No amendments are being filed with this request. This request is being filed with a Notice of Appeal.

Applicants request review because prosecution of the application meets both criteria set forth for the Pre-Appeal Brief Review program. The Final Office Action contains clear errors in the Examiner's rejections and the Examiner has not identified one or more essential claim elements.

Applicants submit that the Final Office Action contains clear error because the Examiner has failed to consider changes made to the claims in Applicants' Amendment and Response filed March 6, 2007. In that paper, Applicants amended composition, device, article, and method claims to just method claims. Yet, with regard to the claims amended from reciting a composition, device or article to reciting a method, the Final Office Action merely recapitulated rejections presented in the prior Office Action, mailed December 6, 2006, without acknowledging the amendment of these claims to recite methods. Thus, either the Examiner has failed to provide fair consideration of Applicants' claims as amended in the March 6, 2006 response, or the Examiner takes the position that new methods for forming a composition, device, or article are unpatentable. Either one constitutes clear error.

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Applicants further submit that the Examiner has not identified the disclosure of one or more claim elements in the prior art and, therefore, has failed to establish a proper rejection under 35 U.S.C. §102 and a *prima facie* case of obviousness under 35 U.S.C. §103. In Applicants' response filed March 6, 2007, certain claims (as noted above) were amended to recite methods. In addition, existing method claims were amended. In all cases, the amendments included method steps that are not taught or suggested in the documents cited in the rejection of the method claims. Yet, the Final Office Action merely recapitulated rejections of the method claims presented in the prior Office Action, mailed December 6, 2006, without consideration of the amendments made in the March 6, 2007 response that recite steps not taught or suggested in the cited documents. Thus, the Examiner has failed to identify one or more elements of Applicants' claims in the prior art. The details of that failure are as follows.

Claims 1-18 and 20-78 stand rejected under 35 U.S.C. §102(b) as being anticipated by Hossainy et al. (U.S. Patent No. 6,153,252). Claims 1-18 and 20-78 further stand rejected under 35 U.S.C. §102(b) as being anticipated by Whitbourne et al. (U.S. Patent No. 6,110,483).

Applicants' claims recite a method that includes some variation of selecting a second polymer to be miscible with a first polymer provided elsewhere in the claim in order form a miscible blend particularly suited for tunable delivery of an active agent.

Hossainy et al. teach polymer coated stents and processes for coating stents. Hossainy et al. teach a variety of considerations that can be used to select polymers: tackiness, adherencce, deformability, toughness, elasticity, melting point (col. 5, lines 39-51), and active agent release rate (col. 7, lines 18-55 and col. 9, lines 26-32). Hossainy et al. neither expressly nor inherently teach selecting polymers based on their miscibility.

Whitbourne et al. teach medicated coatings that can include polymer blends particularly suited for controlling the lubricity, stability, swelling, flexibility, adhesion, and resistance to removal by wet abrasion (col. 9, lines 29-32), some of which may be miscible. Whitbourne et al. neither expressly nor inherently teach selecting miscible polymers particularly suited for controlling the release of active agents.

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In contrast, Applicants' claims recite methods in which the second polymer is expressly, intentionally, and consciously selected to be miscible with the first polymer as opposed to selecting two polymers that merely "are" miscible with one another. The claimed methods include the conscious selection of polymers based on miscibility. Thus, the present claims recite a cognitive and discretionary step that was unknown and, therefore, impossible prior to Applicants' disclosure.

Hossainy et al. and Whitbourne et al. merely recite long laundry lists of general classes of polymers, some of which might be miscible with others. In contrast, Applicants claim methods that include selecting specific types of polymers based on their miscibility. In the absence of evidence that one of the polymer selection criteria specified in Hossainy et al. or Whitbourne et al. necessarily results in selection of miscible polymers, neither Hossainy et al. nor Whitbourne et al. can anticipate Applicants' claims.

The Final Office Action deems the remarks above unpersuasive, stating that each of Hossainy et al. and Whitbourne et al. teaches methods of forming coatings on medical devices that can be comprised of the same polymer blend. Applicants submit that this position set forth in the Final Office Action demonstrates that the Examiner failed to properly consider Applicants' amendments filed March 6, 2007; whether Hossainy et al. and Whitbourne et al. teach similar coatings is irrelevant because Applicants' claims are directed to the method by which the coatings are formed. Applicants' claims recite the cognitive and discretionary step of selecting the second polymer to be miscible with the first polymer.

Neither Hossainy et al. nor Whitbourne et al. teach, expressly or inherently, the step of selecting the second polymer to be miscible with the first polymer and, therefore, neither document can anticipate Applicants' claims. Therefore, Applicants submit that the rejection of Applicants' claims under 35 U.S.C. §102(b) as being anticipated by Hossainy et al. or Whitbourne et al. represents clear error by the Examiner because the cited documents fail to teach, expressly or inherently, a step recited in Applicants' claimed methods.

Claims 1-18 and 20-78 also stand rejected under 35 U.S.C. §103(a) as being unpatentable over Hossainy et al. (U.S. Patent No. 6,153,252). Claims 1-18 and 20-78 stand

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further rejected under 35 U.S.C. §103(a) as being unpatentable over Whitbourne et al. (U.S. Patent No. 6,110,483).

Applicants submit that Hossainy et al. fail to set forth a *prima facie* case of obviousness for claims 1-18 and 20-78 because, at least, Hossainy et al. fail to set forth each and every element of the claims. Applicants further submit that Whitbourne et al. fail to set forth a *prima facie* case of obviousness for claims 1-18 and 20-78 because, at least, Whitbourne et al. fail to set forth each and every element of the claims. The deficiencies of the teachings of Hossainy et al. and Whitbourne et al. are set forth above with regard to the rejections under 35 U.S.C. §102.

The Final Office Action deems Applicants' remarks unpersuasive, stating, "It appears as though applicants are claiming an unknown property (the difference between the two polymers [sic] solubility parameters) of an old combination." This is incorrect and, once again, provides evidence that the Examiner failed to properly consider Applicants' amendments filed March 6, 2007. Applicants are not claiming combinations, but certain methods by which the combinations may be formed. Applicants' claimed methods recite a step that exploits Applicants' discovery—namely, identifying and selecting polymers as being miscible to form a miscible polymer blend for controlling delivery of an active agent. The desirability of doing so was unknown prior to Applicants' disclosure and, therefore, the claimed methods could not have been taught or suggested prior to Applicants' disclosure.

The Final Office Action notes that the Perez document—although not formally presented as part of a rejection—teaches predicting the miscibility of two polymers based on solubility parameters of the polymers. This is relevant only if there is teaching or suggestion to select polymers based on their miscibility. Without such teaching or suggestion, the skilled artisan has no reason to refer to Perez. As stated in the preceding paragraph, Applicants submit that such teaching or suggestion is missing from both Hossainy et al. and Whitbourne et al. Consequently, Applicants submit that Applicants' claims are patentable over Hossainy et al. or Whitbourne et al., whether alone or in combination with Perez.

Therefore, Applicants submit that the rejection of claims 1-18 and 20-78 under 35 U.S.C. §103(a) as being unpatentable over Hossainy et al. or Whitbourne et al. represents clear

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error by the Examiner because the cited documents fail to teach or suggest a step recited in Applicants' claimed methods.

For the foregoing reasons, Appellants respectfully request that the Panel review and reverse the final rejection, dated April 11, 2007, in the above-identified application, and that a Panel Decision allowing the application on the existing claims be issued.

## CERTIFICATE UNDER 37 C.F.R. 1.8:

The undersigned hereby certifies that this paper is being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 11th day of July, 2007, at 4:16 pm (Central Time).

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July 11, 2007  
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